Supreme Court, U.S.
FILED

(2)

No. 96-1857 MAY 19 1997

OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

ROBERT L. HESS,

Petitioner,

v.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Respondent.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Respondent,

v.

SCIMED LIFE SYSTEMS, INC.,
and
ROBERT L. HESS,

Petitioner.

Petition for a Writ Of Certiorari to the United States Court of Appeals for the Federal Circuit

---

APPENDIX A

KEITH V. ROCKEY*
KATHLEEN A. LYONS
Dressler, Rockey, Milnamow & Katz, Ltd.
180 North Stetson Avenue
Suite 4700
Chicago, Illinois 60601
(312) 616-5400

Counsel for Petitioner
*Counsel of Record

59 pp

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1066

ROBERT L. HESS,
Plaintiff-Appellant,
v.
ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Defendant-Appellee.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff/Cross-Complainant Defendant-Appellee,
v.
SCIMED LIFE SYSTEMS, INC.,
Defendant,
and
ROBERT L. HESS,
Cross-Complainant/Appellant.

JUDGMENT

Appeal from a decision of the United States District Court for the Northern District of California in 92-CV-1956 and 93-CV-3438 entered September 1, 1995, Judge Charles A. Legge.

This CAUSE having been heard and considered,

it is ORDERED and ADJUDGED: *AFFIRMED*

ENTERED BY ORDER
OF THE COURT

DATED: February 18, 1997

/s/ Jan Horbaly
JAN HORBALY,
Clerk

ISSUED AS A MANDATE: March 11, 1997

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1066

ROBERT L. HESS,
Plaintiff-Appellant,
v.
ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Defendant-Appellee.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff/Cross-Complainant Defendant-Appellee,
v.
SCIMED LIFE SYSTEMS, INC.,
Defendant,
and
ROBERT L. HESS,
Cross-Complainant/Appellant.

Keith V. Rockey, Dressler, Rockey, Milnamow & Katz, Ltd., of Chicago, Illinois, argued for plaintiff-appellant and cross-complainant/appellant. With him on the brief was *Kathleen A. Lyons*.

Craig B. Bailey, Fulwider Patton Lee & Utecht, of Los Angeles, California, argued for defendant-appellee and plaintiff/cross-complainant defendant-appellee. With him on the brief were *Richard A. Bardin* and *Paul M. Stull*. Of counsel on the brief was *Mark B. Mondry*, Advanced Cardiovascular Systems, Inc., of Santa Clara, California.

Appealed: U.S. District Court for the Northern District of California

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1066

ROBERT L. HESS,
Plaintiff-Appellant,
v.
ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Defendant-Appellee.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff/Cross-Complainant Defendant-Appellee,
v.
SCIMED LIFE SYSTEMS, INC.,
Defendant,
and
ROBERT L. HESS,
Cross-Complainant/Appellant.

DECIDED: February 18, 1997

Before NEWMAN, *Circuit Judge*, FRIEDMAN, *Senior Circuit Judge*, and MICHEL, *Circuit Judge*.

FRIEDMAN, *Senior Circuit Judge*.

This appeal challenges the decision of the United States District Court for the Northern District of California that the materials and suggestions the appellant Robert L. Hess provided to the listed inventors of a patent did not make him a co-inventor of the patented device. We affirm.

I.

A. United States Patent No. 4,323,071 (the '071 patent), which listed Drs. John B. Simpson and Edward W. Robert as the inventors, covers a balloon angioplasty catheter that is inserted into a patient's artery which has a partial blockage, or stenosis. The balloon, fitted to the catheter, is inflated by forcing a radiographic fluid into it under pressure; the resulting expansion of the balloon eliminates or reduces the blockage of the artery.

While developing the catheter, Drs. Simpson and Robert were postdoctoral Cardiology Fellows at Stanford University Medical Center. A Swiss physician, Dr. Gruntzig, had pioneered the development of balloon angioplasty. After hearing Dr. Gruntzig speak at a cardiology conference at Stanford in March 1977 and later meeting him, Dr. Simpson spent time with Dr. Gruntzig in Europe, observing him perform balloon angioplasty procedures.

Upon returning to the United States Dr. Simpson discovered that Gruntzig catheters, made only in Switzerland, were in short supply. Drs. Simpson and Robert then decided to construct their own catheter. They had not examined the Gruntzig catheter in detail, but knew it had a balloon mounted on a shaft.

In attempting to find a material from which a balloon could be made, the doctors first experimented with a plastic called polyvinylchloride, which was ineffective, and next tried Teflon tubing, which produced unsatisfactory balloons. One of their Stanford colleagues (Bill Sanders) then referred them to the appellant Mr. Hess, an engineer at Raychem Corporation. At that time Mr. Hess was a technical liaison between Raychem's domestic and foreign operations; prior to that he had headed a business development group. Sanders made the suggestion because Raychem was one of the largest manufacturers of heat shrinkable materials and "might have some material" with which they could work.

The doctors told Mr. Hess, who had no previous experience with angioplasty, about the Gruntzig catheter. They stated they "wanted to . . . build a catheter . . . that incorporated a balloon on the end of a shaft." They explained what they were attempting to do, the problems they had encountered in finding a suitable material for the balloon, and that they were looking for a new material. They stated that the materials they had tried did not enable them properly to control balloon expansion.

Mr. Hess suggested that the doctors try Raychem's heat shrinkable irradiated modified polyolefin tubing and demonstrated how such a material could be used to form a balloon by heating the tubing above its crystalline melting point, applying pressure, and then cooling the material. Mr. Hess also suggested the use of an adhesive-free seal to attach the balloon to the catheter. He described how one end of the tubing could be shrunk fit onto the central shaft of the catheter without the use of any potentially-toxic adhesive chemicals. Mr. Hess stated that "the basic principles which I taught them"—involving heating the tubing "above its crystalline melting point, expanding it while it remains heated using internal pressure and then cooling it in its expanded state while your [sic] maintaining the pressure"—were "in various published textbooks and the like" and "was a generally known process to a number of companies."

Mr. Hess provided "multiple samples of . . . tubing," with which the doctors "experimented." At that meeting and in further discussions with the doctors, Mr. Hess also suggested "approaches to construction of the catheter" using the Raychem tubing.

Using that tubing, Drs. Simpson and Robert then developed and built their catheter. They had "difficulty . . . developing the . . . catheter" and spent "hours and days trying to configure this system to make it work," including "experimentation . . . with the tubing" Mr. Hess "gave" them. The two doctors worked on the

catheter "virtually every day [for] four or five hours or more." The doctors finally developed the balloon using a technique called free-blowing, a technique which Mr. Hess admittedly did not suggest. Pursuant to Mr. Hess's suggestion, the doctors attempted to avoid the use of adhesives and shrink fit the balloon to the catheter shaft, but they encountered leakage problems. Without Mr. Hess's assistance and after further experimentation, the doctors ultimately developed an acceptable adhesive-free seal. Mr. Hess did not participate in the day-to-day experimentation.

The doctors applied for a patent on their catheter in April, 1978 and the '071 patent issued with twenty-one claims (the "original claims") in April, 1982. The two inventors organized the appellee company Advanced Cardiovascular Systems, Inc. (ACS), to which they assigned the '071 patent, and began manufacturing and selling the catheter. An ACS officer stated that the "catheter gained widespread success in the marketplace, and sales of the product grew rapidly," and that the Simpson-Robert catheter "was profitable" to ACS. Raychem supplied ACS with tubing for manufacturing the catheters.

B. In 1987, ACS sued SciMed Life Systems, Inc. (SciMed) in the United States District Court for the District of Minnesota for infringement of the '071 patent. The district court granted SciMed's motion for summary judgment of non-infringement, based on its interpretation of the claims. This court, however, vacated and remanded, rejecting the district court's claim interpretation. *Advanced Cardiovascular Sys., Inc.* v. *SciMed Life Sys., Inc.*, 887 F.2d 1070, 12 USPQ2d 1539 (Fed. Cir. 1989).

The question of Mr. Hess's alleged co-inventorship apparently first arose when in its answer SciMed asserted, as one ground for challenging the validity of the patent, that there was a "failure of the patentees to join Hess as a co-patentee." In a declaration Mr. Hess executed in 1988, which SciMed filed in the patent infringement case, he described the aid he had given to

Drs. Simpson and Robert in connection with the development of their catheter. In a 1990 affidavit, he repeated those statements and asserted that he "made substantive contributions to the subject matter disclosed" in the '071 patent and "should be named as a co-inventor thereof."

In September, 1987, ACS requested reexamination of certain claims in the '071 patent. In May 1990, the Patent and Trademark Office issued a reexamination certificate, which upheld the original claims and added claims 22-52 (the "reexamination claims").

In the summer of 1990, Mr. Hess intervened in the ACS-SciMed suit to file a cross-complaint against ACS seeking a declaration that he was a joint inventor of the catheter the '071 patent covered and seeking correction of the patent to reflect his status. The district court dismissed Mr. Hess's cross-complaint for failing to state a claim on which relief could be granted because the complaint was barred by laches. This court vacated the dismissal and remanded, holding that there were disputed issues of material fact with respect to laches that precluded dismissal. *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 988 F.2d 1157, 26 USPQ2d 1038 (Fed. Cir. 1993).

While that appeal was pending, Mr. Hess filed suit in United States District Court for the Northern District of California against ACS, alleging that he was a co-inventor of the catheter the reexamination claims covered.

On the eve of trial ACS and SciMed settled their infringement suit. The Minnesota District Court then transferred to the Northern District of California Court the remaining portion of the case, which was Mr. Hess's cross-complaint asserting his co-inventorship of the catheter the '071 patent covers. The California District Court consolidated the two cases.

The California District Court granted summary judgment that Mr. Hess's claim of co-inventorship of the catheter the original claims covered was barred by laches, and set for trial the co-ownership issue with respect to the reexamination claims.

After a bench trial, the district court held that the evidence did not establish Mr. Hess's claim of co-inventorship of the catheter the reexamination claims covered. Ruling from the bench, the court determined that Mr. Hess was required to prove co-inventorship by clear and convincing evidence. The court stated:

> [A]ll that Mr. Hess needs to establish is that he conceived some important element or some important claim that is claimed in the patent . . . .
>
> . . . .
>
> . . . I don't think it's necessary for Mr. Hess to conceive of every feature of the catheter, but that he have some conceptual role in at least an important or a necessary element, or important and necessary claim.

The court noted:

> [I]nventors can obtain the services and ideas and product of others without losing their exclusive right to ownership . . . .
>
> . . . .
>
> So merely that Mr. Hess was consulted, Mr. Hess made some contribution, doesn't in and of itself rise to the level of conception particularly if he's doing nothing more than explaining to the inventors what the then state of the art was and supplying a product to them for use in their invention.

The court found that

> the information provided by Mr. Hess really didn't rise to the level of conception; that most, if not all, of his discussion with them were [sic] telling them what was available in the marketplace by way of product, and telling them how the product worked, and they, that is, Simpson and Robert, were the ones who used the product or used the—yes, used the product provided in their work.
>
> . . . .
>
> [W]hen they were meeting with Mr. Hess, I think what Mr. Hess was doing was showing them available product, telling them its properties, telling them how it could be used, and how it might be used.
>
> . . . Raychem became a supplier of product to Simpson and Robert, really all of which really leaves [sic] me to the conclusion that Mr. Hess' role was really as a representative of Raychem who is making available to a customer or potential customer the product that Raychem has, and its property uses and adaptation to what the inventors here wanted to do.
>
> . . . .
>
> [I]t's [sic] also clear from the record that Mr. Hess didn't know anything about angioplasty or medical catheters until discussion with Dr. Robert and Dr. Simpson.

Finally, the court stated:

> I do wish to state for the record that on a factual basis after having heard the evidence in the case, I'm also concluding that the evidence did not establish coinventorship of the original claims in the '071 patent and not just the reissue claims for that patent.

Hess v. Advanced Cardiovascular Sys., Inc., No. C-92-1956 (N.D. Cal. Feb. 3, 1995).

II.

The patent laws provide that whoever "invents" patentable subject matter is entitled to a patent thereon, 35 U.S.C. § 101 (1994), and that when an "invention" is "made by two or more persons jointly, they shall apply for [a] patent jointly." 35 U.S.C. § 116 (1994). The statute also deals with the situation where an inventor is not named in the application or the issued patent. 35 U.S.C. §§ 116, 256 (1994). Section 256 provides that if "through [inadvertent] error an inventor is not named in an issued patent...the Commissioner [of Patents] may...issue a certificate correcting such error," and that "[t]he court...may order correction of the patent...and the Commissioner shall issue a certificate accordingly."

The district court held that Mr. Hess had to prove his claim of co-inventorship by clear and convincing evidence, and that Mr. Hess had not done so. Mr. Hess challenges both of these rulings.

A. As the Court of Claims (whose decisions bind us, *South Corp. v. United States*, 690 F.2d 1368, 1370, 215 USPQ 657, 658 (Fed. Cir. 1982) (in banc)) stated in *Garrett Corp. v. United States*, 422 F.2d 874, 880, 164 USPQ 521, 526 (Ct. Cl.), *cert. denied*, 400 U.S. 951 (1970), "[t]he burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence." Although the case involved section 116, which governs patent applications, and the present case involves section 256, which covers issued patents, the pertinent statutory language is virtually identical, and the burden of proof on this issue is the same under both sections. *See* 1 Donald S. Chisum, *Patents* § 2.03(4) at 2-31 (1996).

The rule rests on important policy considerations. "The inventors as named in an issued patent are presumed to be correct." *Amax Fly Ash Corp. v. United States*, 514 F.2d 1041, 1047, 182 USPQ 210, 215 (Ct. Cl. 1975). As the court there stated, in holding that one claiming that the inventor listed in the patent derived the invention from the claimant's work must show derivation by clear and convincing evidence, "the temptation for even honest witnesses to reconstruct, in a manner favorable to their own position, what their state of mind may have been years earlier, is simply too great to permit a lower standard." *Id.* at 1047, 182 USPQ at 215 (footnote omitted). This language is similarly applicable to claims of co-inventorship made after a patent has been issued—particularly where, as here, the patent has been outstanding for a considerable time and the patented device has been successful. In that situation, too, there is an equally strong temptation for persons who consulted with the inventor and provided him with materials and advice, to reconstruct, so as to further their own position, the extent of their contribution to the conception of the invention. In these circumstances, it would be inappropriate to permit a lower standard than clear and convincing evidence.

Mr. Hess apparently suggests that because of the particular circumstances of his participation in the activities of Drs. Simpson and Robert, the proper evidentiary standard for determining his co-inventorship claim should be preponderance rather than clear and convincing. Once the standard of proof has been determined, however—and we have held that it is clear and convincing evidence for determining co-inventorship—it applies without regard to the circumstances of a particular case. Permitting the exception Mr. Hess urges could significantly undermine the designated standard of proof, since litigants always can assert, and sometimes effectively, that their cases involve special circumstances.

B. Mr. Hess concedes that the district court "articulat[ed] the appropriate test for inventorship." The district court's standard was whether Mr. Hess "conceived some important element or some important claim that is claimed in the patent," and whether he had "some conceptual role in at least an important or a necessary element, or important and necessary claim." Mr. Hess argues, however, that the court "completely misapplied" that standard "in finding that Hess's contributions were not inventive." This argument, however, is in reality only a reformulation of the contention that the district court's findings upon which the court based its conclusion that Mr. Hess had not established co-inventorship, are clearly erroneous.

We have carefully reviewed the evidence in the record. Although there is some conflict on the question of co-inventorship, the district court's findings that Mr. Hess was not a co-inventor of the catheter claimed in the '071 patent are not clearly erroneous.

When Drs. Simpson and Robert first met with Mr. Hess, he was totally unfamiliar with angioplasty catheterization and the problems it involved. They explained to him what they were trying to do, and what difficulties they encountered. He recommended a Raychem product that he believed would be suitable for making a balloon, showed them how a balloon could be formed by heating both ends of the tube (a procedure they did not use in making their patented catheter, and made other suggestions for making the catheter, using the Raychem tubing. Although the doctors followed and utilized some of Mr. Hess's suggestions in their extensive further research, testing and construction of their catheter, the district court justifiably concluded on this record that it was they, and not Mr. Hess, who actually conceived and made the patented invention and that Mr. Hess's contributions to the inventions did not constitute the conception necessary to establish co-inventorship.

More than 140 years ago the Supreme Court, in holding that Samuel Morse's discussions with scientists in connection with his invention of the telegraph did not alter his status of the sole inventor of that device, stated:

> No invention can possibly be made, consisting of a combination of different elements ... without a thorough knowledge of the properties of each of them, and the mode in which they operate on each other. And it can make no difference, in this respect, whether [the inventor] derives his information from books, or from conversation with men skilled in the science. If it were otherwise, no patent, in which a combination of different elements is used, could ever be obtained.

O'Reilly v. Morse, 56 U.S. 62, 111 (1853).

Similarly, in *Shatterproof Glass*, this court stated that

> [a]n inventor "may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent."

Shatterproof Glass Corp. v. *Libbey-Owens Ford Co.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (quoting *Hobbs* v. *United States Atomic Energy Comm'n*, 451 F.2d 849, 864, 171 USPQ 713, 724 (5th Cir. 1971)).

Mr. Hess relies on the following statement in the 1914 district court opinion in *DeLaski & Thropp Circular Woven Tire Co.*v. *William R. Thropp & Sons Co.*, 218 F. 458, 464 (D.N.J., 1914), *aff'd*, 226 F. 941 (3d Cir. 1915), which he describes as "the controlling legal standard."

> The conception of the entire device may be due to one, but if the other makes suggestions of practical value, which assisted in working out the main idea and making it operative, or contributes an independent part of the

> entire invention, which is united with the parts produced by the other and creates the whole, he is a joint inventor, even though his contribution be of comparatively minor importance and merely the application of an old idea.

That language, of course, is not binding precedent in this court, and its focus appears inconsistent with the approach the Supreme Court took in *Morse* and this court took in *Shatterproof Glass*. In any event, whether particular suggestions and contributions of third persons amount to co-inventorship turns on the facts of the particular case.

Here the district court found that in his consultations with Drs. Simpson and Robert, Mr. Hess was "doing nothing more than explaining to the inventors what the then state of the art was and supplying a product to them for use in their invention"; that "most, if not all, of his discussion with them were [sic] telling them what was available in the marketplace by way of product, and telling them how the product worked"; and that "what Mr. Hess was doing was showing them available product, telling them its properties, telling them how it could be used, and how it might be used." The principles Mr. Hess explained to them were well known and found in textbooks. Mr. Hess did no more than a skilled salesman would do in explaining how his employer's product could be used to meet a customer's requirements. The extensive research and development work that produced the catheter was done by Drs. Simpson and Robert. Our review of the record satisfies us that those findings are not clearly erroneous, and that they support the district court's conclusion that whatever contribution Mr. Hess made to Drs. Simpson and Robert did not constitute conception and therefore did not make Mr. Hess a co-inventor of the catheter claimed in the '071 patent.

Mr. Hess relies on snippets of the doctors' testimony in which, he asserts, the doctors conceded that Mr. Hess was

responsible for significant portions of the invention the '071 patent disclosed. Those statements, however, cannot bear the weight Mr. Hess gives them. In the context of the entire record, they do not refute the factual sufficiency of the evidence supporting the district court's decision.

III.

Mr. Hess also argues that the district court erroneously dismissed on summary judgment, as barred by laches, that portion of his case that claimed co-inventorship of the invention disclosed in the original claims. That issue, however, is moot in view of the district court's ruling that "on a factual basis after having heard the evidence in the case, I'm also concluding that the evidence did not establish coinventorship of the original claims in the '071 patent and not just the reissue claims for that patent." Accordingly, we do not consider it.

CONCLUSION

The judgment of the district court that Mr. Hess has not established his claim to co-inventorship of the catheter disclosed in the '071 patent is

AFFIRMED.

Judge Legge

RICHARD A. BARDIN
CRAIG B. BAILEY
PAUL M. STULL
FULWIDER PATTON LEE &
UTECHT
10877 Wilshire Boulevard,
Tenth Floor
Los Angeles, California 90024
(310) 824-5555

Attorneys for Defendant
Advanced Cardiovascular
Systems, Inc.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ROBERT L. HESS,
Plaintiff,

vs.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Defendant.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff,

vs.

SCIMED LIFE SYSTEMS, INC.,
Defendant.

ROBERT L. HESS,
Intervenor.

CONSOLIDATED CASE NOS.
C-92-1956 CAL; and
C-93-3438 CAL

FINAL JUDGMENT

These consolidated actions having come on for trial before this Court, Honorable Charles A. Legge presiding, and the issues having been duly tried and the Court having stated its findings of fact and conclusions of law in open court on July 26, 1995, as reflected in the Reporter's Transcript of the Proceedings thereon, it is Ordered and Adjudged as follows:

1. This Court has jurisdiction over the parties and the cause of action, and venue is not disputed.

2. Robert L. Hess ("Hess") is barred by laches from establishing any rights of inventorship or co-inventorship of the subject matter of any of the claims 1-21 of U.S. Patent No. 4,323,071 to Simpson et al. ("the '071 patent") for the reasons previously stated in open court on February 3, 1995, as reflected in the Reporter's Transcript of the proceeding on that date.

3. Hess failed to prove at trial that he is an inventor or co-inventor of added claims 22-52 of Reexamination Certificate B1 4,323,071 of the '071 patent. Therefore, Hess shall take nothing by way of these consolidated actions, and his complaint in Case No. C-92-1956 CAL and his complaint-in-intervention in Case No. C-93-3438 CAL are each hereby dismissed with prejudice.

4. The evidence would not be any different if the question of inventorship of claims 1-21 of the '071 patent had been tried, and such evidence fails to prove that Hess is an inventor or co-inventor of the subject matter of those claims.

5. ACS shall have judgment as to its counterclaims in Case Nos. C-92-1956 CAL and C-93-3438 CAL against Hess seeking declarations that Hess is not an inventor or co-inventor of the subject matter of any of claims 1-52 of the '071 patent.

6. ACS shall recover from Hess its costs herein.

7. In view of the foregoing, there being no other matter remaining to be determined and there being no just reason for delay, these judgments shall be deemed final.

(September 1 sn)

Dated: August __, 1995

/s/ Charles A. Legge
HONORABLE CHARLES A. LEGGE
United States District Court Judge

Prepared by:

FULWIDER PATTON LEE & UTECHT

By: /s/ Paul M. Stull
Paul M. Stull
Attorneys for Defendant,
ADVANCED CARDIOVASCULAR
SYSTEMS, INC.

Approved as to form:

ROCKEY, RIFKIN AND RYTHER

By: /s/ Keith V. Rockey
Attorneys for Plaintiff,
ROBERT L. HESS

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA BEFORE THE HONORABLE CHARLES A. LEGGE, JUDGE

ROBERT HESS,
Plaintiff,
vs.
ADVANCED CARDIOVASCULAR SYSTEMS,
Defendant.

No. C-92-1956 CAL

WEDNESDAY, JULY 26, 1995

SAN FRANCISCO, CALIFORNIA

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff,
vs.
SCIMED LIFE SYSTEMS,
Defendant.

No. C-93-3438 CAL

REPORTER'S TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

For Plaintiff Hess:
KEITH V. ROCKEY, ESQUIRE
KATHLEEN A. LYONS, ESQUIRE
Rockey, Rifkin and Ryther
20 South Clark Street
Chicago, IL 60603

Reported By:
DIANE E. SKILLMAN,
Official Court Reporter, USDC

For Defendant Advanced Cardiovascular Systems:
CRAIG B. BAILEY, ESQUIRE
PAUL M. STULL, ESQUIRE
Fulwider Patton Lee & Utecht
10877 Wilshire Blvd.
Los Angeles, CA 90024

URGE THE COURT TO DO SO.

AND I THINK THAT CONCLUDES MY REMARKS.

THE COURT: OKAY. DOES THE MATTER STAND SUBMITTED?

ALL RIGHT. I'M GOING TO STATE MY DECISIONS HERE FOR THE RECORD RIGHT HERE IN OPEN COURT THIS AFTERNOON. I DON'T THINK THERE IS ANY NECESSITY FOR ME TAKING THE MATTER UNDER ANY LENGTHY SUBMISSION.

THE TRIAL HAS BEEN QUITE RECENT AND YOUR BRIEFS HAVE BEEN COMPLETED. AND AS I WILL STATE, I DON'T THINK REALLY THE MATTERS AT ISSUE ARE REALLY ALL THAT COMPLICATED AND I DON'T THINK THAT FURTHER WORK ON MY PART IN THE CLOISTER CONTEMPLATION OF CHAMBERS WOULD REALLY DO ANY GOOD AT ALL.

SO I THINK I AM AS FULLY PREPARED TO RESOLVE THE MATTER TODAY AS I COULD BE ON FURTHER STUDY. I HAVE REVIEWED THE RECORDS, THE TRIAL, AS WELL AS THE MATERIAL YOU SUBMITTED TO ME POST TRIAL.

NOW, FIRST OF ALL, JURISDICTION HERE IS PROPER HERE UNDER 35 U.S.C. SECTION 256 AND 28 U.S.C. SECTION 1338. I DON'T BELIEVE THERE IS ANY DISPUTE OF JURISDICTION. NOR DO I BELIEVE THAT THERE IS ANY DISPUTE REGARDING THE VENUE BEING PROPER HERE UNDER THE APPROPRIATE STATUTE, WHICH I BELIEVE IS 1391.

WE'RE DEALING WITH TWO CASES HERE. THE MAIN ONE BEING 92-1956, BUT WE ALSO HAVE

93-3438. I BELIEVE THAT THE CASES, AT LEAST INSOFAR AS THEY INVOLVE MR. HESS ON ONE SIDE

AND THE DEFENDANT OR DEFENDANTS ACS ON THE OTHER SIDE HAVE BEEN CONSOLIDATED, OR AT LEAST CONSOLIDATED FOR TRIAL.

THE TRIAL HAS BEEN CONDUCTED. IT HAS BEEN A NONJURY TRIAL. I'M NOT SURE WHETHER THE PARTIES ENDED UP STIPULATING TO NONJURY TRIAL OR NOT, BUT EVEN IF THEY DID NOT, I BELIEVE THE PRINCIPAL RELIEF HERE IS EQUITABLE RELIEF, AND IN ADDITION, THE RECENT DECISION OF THE UNITED STATES SUPREME COURT DETERMINING THAT THE APPROPRIATE DECIDER OF FACTS FOR PATENT MATTERS INVOLVING CLAIM INTERPRETATION IS THE COURT AND NOT A JURY. AND IN ORDER TO DECIDE INVENTORSHIP, I THINK IT IS, HAS BEEN, AND WILL BE NECESSARY FOR ME TO INTERPRET CLAIMS OF BOTH THE PATENT AND THE REISSUE CERTIFICATE.

NOW AS I'VE SAID, JUST TO REPEAT A COUPLE OF MATTERS SO THE RECORD IS COMPLETE. I'VE READ THE TESTIMONY OF THE WITNESSES. I'VE READ ALL OF THE EXHIBITS. I'VE READ THE POST TRIAL MATERIAL YOU SUBMITTED TO ME, INCLUDING THE ADDITIONAL PORTIONS OF THE DEPOSITION OF MR. HESS. AND I'VE, AS I SAID, READ YOUR BRIEFS AND READ THE LAW FROM THE BRIEFS AND READ THE CASES AND STATUTES AS I BELIEVE NECESSARY.

SO MY STATEMENTS HERE ON THE RECORD WILL CONSTITUTE THE FINDINGS OF FACT AND

CONCLUSIONS OF LAW THAT I AM MAKING IN CONNECTION WITH THE CASE AND WILL BE AN ORDER FOR THE ENTRY OF THE JUDGMENT.

NOW, THE PRINCIPAL ISSUE WE'RE CONFRONTED WITH HERE IS WHETHER MR. HESS IS AN INVENTOR OR COINVENTOR OF SOME OR

ALL OF THE CLAIMS IN THE OS — IN THE '071 PATENT AND IN THE REEXAMINATION CERTIFICATE UNDER THE '071 PATENT.

THE STATUTORY BASIS FOR THAT KIND OF A CLAIM IS SET FORTH IN TITLE 35 SECTION 256. SO THE ISSUE, AT LEAST IN ITS DEFINITION, IS A VERY NARROW ONE, AND THAT IS, DID — WAS MR. HESS AN INVENTOR OR COINVENTOR WITH RESPECT TO SOME OR ALL OF THE CLAIMS. THAT IS THE ISSUE, THE CENTRAL ISSUE.

I THINK THAT ALL OF THE OTHER ISSUES IN THE CASE ARE EITHER MADE MOOT BY IT OR FLOW FROM IT, INCLUDING CLAIMS THAT I HAVE SEVERED AND STAYED FOR FURTHER CONSIDERATION.

NOW, FIRST OF ALL, I BELIEVE IT'S APPROPRIATE TO DEFINE THE LEGAL STANDARDS UNDER WHICH I'M VIEWING THE EVIDENCE AND MAKING THE DECISIONS.

FIRST OF ALL, THERE IS A PRESUMPTION THAT THE INVENTORS NAMED IN THE ISSUED PATENT ARE CORRECT. I DON'T BELIEVE I NEED TO, REALLY NEED TO CITE ANY CASE LAW OR STATUTORY LAW FOR THAT PROPOSITION, AND IT HAS BEEN

REPEATED MANY TIMES, SO I WILL NOT ADD ANY CASE CITATIONS HERE.

WHAT IS THE LEGAL STANDARD FOR WHEN SOMEBODY IS OR IS NOT AN INVENTOR? I THINK YOU BOTH AGREE THAT THE BASIC ONE, THE ESSENTIAL STEP IS CONCEPTION, AND I THINK YOU BOTH USE THE DEFINITION IN *SEWALL VERSUS WALTERS*, A RECENT DECISION OF THE FEDERAL CIRCUIT AS THE BASIS FOR THAT DEFINITION. I ALSO PICKED UP ON THE SAME THING IN THE *IDACON* CASE IN THE DISTRICT COURT OF OKLAHOMA WITH AN EARLIER DATE.

54

NOW THE QUESTION, AT LEAST I THOUGHT IT WAS A QUESTION, WHEN — FROM THE BRIEFING, IS TO WHAT MR. HESS NEEDS TO HAVE CONCEPTUALIZED IN ORDER TO BE AN INVENTOR.

IT WAS MY UNDERSTANDING OF DEFENDANT'S POSITION THAT HE COULD NOT BE A COINVENTOR UNLESS HE HAD, SHALL WE SAY QUOTE "CONCEIVED" OF THE COMPLETED CATHETER ASSEMBLY, INCLUDING EVERY INDIVIDUAL FEATURE OF IT.

I'M NOT SURE THAT THAT'S THE POSITION THAT WAS JUST ARTICULATED A FEW MINUTES AGO BY MR. BAILEY, BUT IN ANY EVENT, I THINK THAT ALL THAT MR. HESS NEEDS TO ESTABLISH IS THAT HE CONCEIVED SOME IMPORTANT ELEMENT OR SOME IMPORTANT CLAIM THAT IS CLAIMED IN THE PATENT, AND NEED NOT HAVE SAT DOWN AND SAYS HERE IS WHAT THE WHOLE DEVICE IS GOING TO LOOK LIKE WHEN WE'RE FINISHED.

I THINK THAT CONCLUSION, THAT IS, THAT THE PLAINTIFF'S BURDEN IS WITH RESPECT TO SOME IMPORTANT ELEMENT OR SOME IMPORTANT CLAIM IS REALLY WHAT IS CONTEMPLATED IN THE ENTIRE DEFINITION OF THE JOINT OWNERSHIP CONCEPT IN THE STATUTE 35 U.S.C. SECTION 116, AND IN THE EARLIER *MONSANTO VERSUS KAMP* DECISION, WHICH I THINK IS PROBABLY PICKED UP BY CONGRESS AND MADE INTO THAT SECTION 116.

SO, I DON'T THINK IT'S NECESSARY FOR MR. HESS TO CONCEIVE OF EVERY FEATURE OF THE CATHETER, BUT THAT HE HAVE SOME CONCEPTUAL ROLE IN AT LEAST AN IMPORTANT OR A NECESSARY ELEMENT, OR IMPORTANT AND NECESSARY CLAIM.

55

NOW, THAT HAVING BEEN SAID, IT IS NOT, OF COURSE, EVERY COMMUNICATION BY THESE NAMED INVENTORS WITH MR. HESS THAT WILL LEAD TO A CO-OWNERSHIP CONCLUSION. I THINK IT'S QUITE CLEAR THAT INVENTORS CAN OBTAIN THE SERVICES AND IDEAS AND PRODUCTS OF OTHERS WITHOUT LOSING THEIR EXCLUSIVE RIGHT TO OWNERSHIP, AND IN THAT CONTEXT, WE GET BACK TO THE BASIC IDEA OF A CONCEPTION OF AN IMPORTANT ELEMENT OF THE CLAIMS.

I THINK IT'S ALSO TRUE THAT IN THIS CONSULTING WITH OTHERS, BEING TAUGHT THE CURRENT STATE OF THE ART ON SOMETHING OR THE SUPPLYING OF A PARTICULAR PRODUCT FOR USE IS NOT NECESSARILY CONCEPTION. I THINK THAT'S BEEN MADE CLEAR AGAIN RECENTLY BY THE

SEWALL DECISION OF THE FEDERAL CIRCUIT AND EARLIER BY THIS *IDACON* CASE OF THE OKLAHOMA DISTRICT, WHICH I QUOTED EARLIER.

SO MERELY THAT MR. HESS WAS CONSULTED, MR. HESS MADE SOME CONTRIBUTION, DOESN'T IN AND OF ITSELF RISE TO THE LEVEL OF CONCEPTION PARTICULARLY IF HE'S DOING NOTHING MORE THAN EXPLAINING TO THE INVENTORS WHAT THE THEN STATE OF THE ART WAS AND SUPPLYING A PRODUCT TO THEM FOR USE IN THEIR INVENTION.

WE ALSO HAVE A SUBSPAN ON THE APPROPRIATE STANDARD WHERE WE'RE DEALING WITH DEPENDENT CLAIMS AS WE ARE IN THE REISSUE CERTIFICATE. AND THAT IS THAT CERTAIN FEATURES RECITED IN THE DEPENDENT CLAIMS ARE NOT NECESSARILY INVENTIVE FEATURES OVER AND ABOVE THE INDEPENDENT CLAIMS THEMSELVES.

SO, THAT HAVING BEEN SAID, THOSE I BELIEVE ARE THE

56

LEGAL STANDARDS AND THE LEGAL PRINCIPLES TO BE APPLIED — TO WHICH THE EVIDENCE HAS TO BE APPLIED.

NOW WHAT ABOUT THIS BURDEN OF PROOF? THERE IS NO DOUBT THAT THE BURDEN OF PROOF IS ON MR. HESS. AND THE QUESTION ARISES WHETHER IT IS A PREPONDERANCE OF THE EVIDENCE STANDARD OR A CLEAR AND CONVINCING STANDARD. I THINK THAT THE STANDARD IS A CLEAR AND CONVINCING STANDARD.

CERTAINLY SEVERAL CASES HAVE SAID THAT. MR. HESS' COUNSEL CALLS THAT INTO DOUBT BY CITATION TO THE *AMERICAN HOIST* DECISION. HOWEVER, EVEN AFTER THAT CITATION OF *AMERICAN HOIST*, *AMERICAN HOIST* ITSELF GOES ON TO STATE AS FOLLOWS.

> I QUOTE: "INDEED NEW PRIOR ART NOT BEFORE THE PTO MAY SO CLEARLY INVALIDATE A PATENT, BUT THE BURDEN IS FULLY SUSTAINED MERELY BY PROVING ITS EXISTENCE AND APPLYING THE PROPER LAW: BUT THAT HAS NO EFFECT ON THE PRESUMPTION OR ON WHO HAS THE BURDEN OF PROOF. NEITHER DOES THE STANDARD OF PROOF CHANGE; IT MUST BE BY CLEAR AND CONVINCING EVIDENCE OR ITS EQUIVALENT BY WAY OF A FORM OF WORDS IT MAY BE EXPRESSED." END OF QUOTE.

NOW I DON'T THINK THAT IS LIMITED TO A PRIOR ART CASE. I THINK THE SAME THING APPLIES TO AN INVENTORSHIP CASE. SO I BELIEVE THAT THE APPROPRIATE STANDARD IS ONE OF CLEAR AND CONVINCING EVIDENCE. AND WHERE I STATE FACTS HERE, THEY ARE STATED TO BE

57

FACTS WHERE APPROPRIATE BY THIS CLEAR AND CONVINCING STANDARD.

NOW CERTAIN OF THE FACTS IN THE CASE ARE UNCONTESTED, AND WITHOUT REPEATING THOSE, I'LL SIMPLY INCORPORATE BY REFERENCE THE STATEMENT OF UNDISPUTED FACTS THAT IS SET FORTH IN THE JOINT PRETRIAL STATEMENT ON PAGES 8 THROUGH 10.

NOW AS TO THE FACTS IN CONTEST, EVEN AFTER ALL OF THIS WORK DONE BY COUNSEL ON BOTH SIDES, TESTIMONY BY THE WITNESSES, AND THE VOLUMES OF PAPER WE HAVE HERE, THERE DOESN'T REALLY SEEM TO BE MUCH OR MANY TRUE CONFLICTS IN THE EVIDENCE IN THE SENSE OF WHICH THE COURT NORMALLY DEALS WITH.

IN FACT, I FIND VERY FEW CONFLICTS ON THE KEY POINTS IN THIS CASE, AND THAT IS, WHAT DID MR. HESS DO WITH RESPECT TO THIS INVENTION.

MOSTLY THE ISSUE COMES DOWN TO CONCLUSIONS OF FACT OR CONCLUSIONS OF LAW TO BE DRAWN FROM THE FACTS THAT THE WITNESSES WERE REALLY NOT DEBATING ABOUT.

I BELIEVE REALLY THE ONLY MATERIAL TRUE CONFLICT IN THE TESTIMONY WAS THE CONFLICT BETWEEN DR. SIMPSON AND DR. ROBERT ON THE ONE HAND AND DR. HESS ON THE OTHER AS TO WHO FIRST CAME UP WITH THE COAXIAL IDEAS.

ALL RIGHT. THEN APPLYING WHAT THE EVIDENCE IS TO THE . . . WITH THAT BURDEN OF PROOF AND TO THE STANDARD OF LAW, I HAVE TO FIRST REACH THE GENERAL CONCLUSION THAT MR. HESS HAS NOT BEEN ABLE TO SUSTAIN HIS BURDEN OF PROOF IN THE APPLICABLE LEGAL STANDARD.

58

I DON'T BELIEVE THAT HE HAS DEMONSTRATED UNDER THE APPLICABLE BURDEN OF PROOF THE CONCEPTION AS THAT CASE — AS THAT PRINCIPLE HAS BEEN DEFINED AS TO AN IMPORTANT ELEMENT OR IMPORTANT CLAIM OF THE INVENTION.

I THINK WHAT WE HAVE IS, WITH RESPECT TO MOST OF IT IS WHERE IN DEED DR. ROBERTS — DR. ROBERT, DR. SIMPSON DID GO TO MR. HESS, DID GO TO RAYCHEM, BUT THAT THE INFORMATION PROVIDED BY MR. HESS REALLY DIDN'T RISE TO THE LEVEL OF CONCEPTION; THAT MOST, IF NOT ALL, OF HIS DISCUSSION WITH THEM WERE TELLING THEM WHAT WAS AVAILABLE, IN THE MARKETPLACE BY WAY OF PRODUCT, AND TELLING THEM HOW THE PRODUCT WORKED, AND THEY, THAT IS, SIMPSON AND ROBERT, WERE THE ONES WHO USED THE PRODUCT OR USED THE — YES, USED THE PRODUCT PROVIDED IN THEIR WORK.

I THINK THAT PRINCIPLE ALSO APPLIES TO THE CONCEPT OF TEACHING THE PRIOR ART AND THE — I'M REPEATING MYSELF, I GUESS, MAKING ALREADY AVAILABLE PRODUCT AVAILABLE TO THE INVENTORS.

NOW, IN ALL OF THIS, I DO NOT MEAN TO DEMEAN IN ANY WAY MR. HESS' INTEGRITY OR HIS INTELLIGENCE OR HIS OWN INGENUITY OR HIS COMPETENCE AS A WITNESS OR HIS HONESTY AS A WITNESS.

I THINK THE FACTS WERE THE FACTS, AND I THINK THEY WERE VERY CLEARLY SET FORTH AND MR. HESS CERTAINLY HAD A ROLE IN THIS.

59

I THINK THAT ROLE IS PROBABLY DEFINED AS WELL AS ANYBODY COULD DEFINE IT IN EXHIBIT 31, WHICH I BELIEVE IS THE NUMBER OF THE LETTER FROM DR. SIMPSON TO RAYCHEM WHICH CERTAINLY COMPLIMENTS MR. HESS.

THAT LETTER IS PERHAPS A BIT OF EMBARRASSMENT TO THE DEFENDANTS IN THE CONTEXT OF THIS CASE, BUT IT DOES STATE TO A DEGREE OF ACCURACY MR. HESS' PARTICIPATION AND I THINK IT'S BLOWING ALL THE SMOKE AT RAYCHEM FOR THE GENERAL IDEA OF INVOLVING RAYCHEM IN FUTURE DEVELOPMENTS, IT'S OVERSTATING THE CASE, BUT NEVERTHELESS IT IS CLEARLY SOME DEBT OF GRATITUDE AT LEAST BY SIMPSON AND ROBERT TO MR. HESS, ALBEIT I'M FINDING THAT THAT IS NOT A DEBT THAT RISES TO A LEVEL OF BEING A COINVENTOR.

I WANT TO MAKE A FEW COMMENTS BY WAY OF FACTUAL FINDINGS OR JUST COMMENTING ON THE EVIDENCE WITH RESPECT TO A FEW THINGS.

FIRST OF ALL, THE THREE ELEMENTS WHICH MR. ROCKEY HAS ARGUED REALLY AREN'T IN DISPUTE. THAT IS THE FEATURES, LET'S CALL IT, THAT MR. HESS CONSULTED WITH DR. SIMPSON AND DR. ROBERT ABOUT. AND THAT IS THE MATTER DEALING WITH THE MATERIALS, THE SHAPING OF IT INTO THE BALLOON, AND THE HEAT-SHRINK PROPERTY AND USES OF HEAT-SHRINK TUBING INCLUDING THE ABILITY TO SEAL A TUBING AROUND THE ROD WITHOUT THE USE OF AN ADHESIVE.

NOW IT SEEMS TO ME WHAT THIS SITUATION REALLY JUST

IS NOT INVENTORSHIP. IT MAY HAVE A CERTAIN DEGREE OF INGENIOUSNESS TO IT, BUT THAT IS NOT INVENTORSHIP. THAT IS, RAYCHEM HAD THIS PRODUCT. HEAT-SHRINK TUBING WAS ON THE

MARKET. IT MAY NOT BE KNOWN TO SIMPSON AND ROBERT, BUT IT WAS A PRODUCT RAYCHEM HAD BEEN MAKING, AND SOMEBODY KNEW ABOUT IT. THEY WERE REFERRED SPECIFICALLY TO, I THINK — THERE IS A SMALL CONFUSION IN THE EVIDENCE HERE AS TO EITHER SPECIFICALLY MR. HESS OR RAYCHEM GENERALLY, TO SEE IF HEAT-SHRINK TUBING COULDN'T DO THE JOB.

SO WHEN THEY WERE MEETING WITH MR. HESS, I THINK WHAT MR. HESS WAS DOING WAS SHOWING THEM AVAILABLE PRODUCT, TELLING THEM ITS PROPERTIES, TELLING THEM HOW IT COULD BE USED, AND HOW IT MIGHT BE USED. SO I REALLY DON'T THINK — WELL, IN ADDITION, I THINK IT IS SIGNIFICANT THAT THE PATENT ITSELF DISCLOSES THE RAYCHEM MATERIAL AS BEING PART OF THE PRIOR ART IN THE CASE.

AND IN ADDITION, THERE WERE LATER MEETINGS BETWEEN SIMPSON AND ROBERT ON THE ONE HAND AND RAYCHEM PEOPLE ON THE OTHER OBVIOUSLY LEADING TO THE RELATIONSHIP WHERE RAYCHEM BECAME A SUPPLIER OF PRODUCT TO SIMPSON AND ROBERT, REALLY ALL OF WHICH REALLY LEAVES ME TO THE CONCLUSION THAT MR. HESS' ROLE WAS REALLY AS A REPRESENTATIVE OF RAYCHEM WHO IS MAKING AVAILABLE TO A CUSTOMER OR POTENTIAL, CUSTOMER THE PRODUCT THAT RAYCHEM HAS, AND ITS PROPERTY USES AND ADAPTATION TO WHAT THE INVENTORS HERE WANTED TO DO. ALL OF WHICH IS IMPORTANT, BUT I

DON'T THINK RISING TO THE LEVEL OF INVENTORSHIP.

I WOULD ALSO NOTE THAT ALL THE PHYSICAL WORK ON THE DEVICE WAS DONE BY DR. SIMPSON AND DR. ROBERT, INCLUDING THE TESTING.

NOW, ONE DOESN'T HAVE TO ACTUALLY DO THE PHYSICAL WORK ON THE OBJECT IN ORDER TO BE THE INVENTOR, BUT I DO THINK IT HAS SOME EVIDENTIARY VALUE; THAT IT WAS DR. SIMPSON AND DR. ROBERT WHO REALLY WERE WORKING HARD, HARD WORKING AT THE BENCH.

I THINK IT'S ALSO CLEAR FROM THE RECORD THAT MR. HESS DIDN'T KNOW ANYTHING ABOUT ANGIOPLASTY OR MEDICAL CATHETERS UNTIL DISCUSSION WITH DR. ROBERT AND DR. SIMPSON.

ON THE QUESTION OF WHO HAD THE IDEA FOR THE COAXIAL RELATIONSHIP FOR THE CATHETER, THERE IS, AS I SAID, A CONFLICT IN THE EVIDENCE HERE AND ONE WHICH MR. HESS BEARS BY CLEAR AND CONVINCING EVIDENCE, AND I JUST DON'T THINK THE EVIDENCE CAN DO THAT.

THE TESTIMONY — REALLY THE TESTIMONY ON BOTH SIDES AS FAR AS DIRECT TESTIMONY ON THE QUESTION IS ALL VERBAL. IT'S ALL PEOPLE SAYING WHAT OCCURRED HOW MANY YEARS AGO. I REALLY FIND NO CONTEMPORANEOUS EVIDENCE IN THE FORM OF NOTES OR ANYTHING LIKE THAT TO CORROBORATE EITHER POSITION.

THE DIFFERENCES IN THE TIME LINES AS PEOPLE RECALL THEM AS MAYBE INDICATED BY WHAT

PAPER TRAIL WE DO HAVE ON THE TIME LINE IS REALLY NOT ALL THAT IMPORTANT. THE QUESTION IS

62

WHO, NOT WHEN.

AND AS I BELIEVE THE DEFENSE HAS ARGUED HERE, THAT THESE EVENTS UNDER THE DEVELOPMENT OF THE CATHETER WERE IMPORTANT IN THE WORKING LIVES OF DRS. SIMPSON AND ROBERT AT THE TIME, AND INDEED — ALTHOUGH THEY WERE DOING THIS ON A PART TIME BASIS, IT WAS CERTAINLY AN OVERWHELMING ASPECT OF THEIR DAILY LIFE, WHILE MR. HESS AT THE TIME INQUIRY REALLY SEEMED TO BE MORE TANGENTIAL TO OTHER WORK HE WAS DOING FOR RAYCHEM.

BUT I THINK THIS FALTERS — MR. HESS' POSITION FALTERS ON THIS NOT FROM WHAT I BELIEVE OR DON'T BELIEVE, BUT FROM THE BURDEN OF PROOF BEING ONE OF CLEAR AND CONVINCING EVIDENCE, AND SIMPLY FACED WITH CONFLICTING TESTIMONY OF THREE WITNESSES WITH WHAT I BELIEVE TO BE NO REAL CORROBORATION OUTSIDE THAT TESTIMONY. I JUST DON'T THINK MR. HESS CAN CARRY HIS BURDEN OF NO CLEAR AND CONVINCING EVIDENCE.

I'M ALSO GIVING SOME CREDENCE AND THE WEIGHT OF THE TESTIMONY AND THE INTERPRETATION OF IT TO THE LENGTH OF TIME THAT WENT ON HERE AFTER THE DEVELOPMENT AND BEFORE MR. HESS ASSERTED HIS CLAIMS — MADE HIS CLAIMS, AND THE CONTEXT IN WHICH THEY WERE FIRST ASSERTED.

NOW, WHETHER THIS IS OR IS NOT LACHES, OR THIS IS OR IS NOT ESTOPPEL IS NOW MOOT BECAUSE OF MY DECISION THAT HE'S NOT A COINVENTOR, BUT I DO THINK THAT THE LENGTH OF TIME HAS SOME SORT OF EVIDENTIARY VALUE HERE AND I THINK IS A FACTOR IN

63

WEIGHT BEING GIVEN TO SOME OF THE EVIDENCE.

SO, SINCE I AM FINDING THAT — FOR THE DEFENDANTS ON THE ISSUE — REALLY DEFENDANT ON THE ISSUE OF INVENTORSHIP WHICH IS A FACTUAL QUESTION, I AM NOT GOING TO MAKE ANY FURTHER RULING ON DEFENDANT'S AFFIRMATIVE DEFENSES SUCH AS STATUTE OF LIMITATIONS, AND LACHES, AND ESTOPPEL.

AND I ALSO THINK THAT IN VIEW OF MY CONCLUSIONS HERE WITH RESPECT TO THE HISTORY OF THE ENTIRE INVENTORSHIP, THAT EVEN INSOFAR AS THE CASE PERTAINS TO THE ORIGINAL CLAIMS AND NOT JUST THE REISSUE CLAIMS, THAT MY FINDINGS AND MY CONCLUSIONS WOULD BE ESSENTIALLY THE SAME.

I DON'T THINK THE EVIDENCE WOULD BE ANY DIFFERENT IF WE WERE RETRYING THE ORIGINAL ISSUE CASE, SO ALTHOUGH I ORIGINALLY DECIDED THE MOTION FOR PARTIAL SUMMARY JUDGMENT IN FAVOR OF DEFENDANT ON THE BASIS OF LACHES AND ESTOPPEL, I DO WISH TO STATE FOR THE RECORD THAT ON A FACTUAL BASIS AFTER HAVING HEARD THE EVIDENCE IN THE CASE, I'M ALSO CONCLUDING THAT THE EVIDENCE DID NOT ESTABLISH COINVENTORSHIP OF THE ORIGINAL

CLAIMS IN THE '071 PATENT AND NOT JUST THE REISSUE CLAIMS FOR THAT PATENT.

SO I AM DIRECTING THAT JUDGMENT BE ENTERED IN 92-1956 IN FAVOR OF DEFENDANT AND AGAINST THE PLAINTIFF ON THE SECOND AMENDED COMPLAINT AS TO COUNT 2 THAT IS BASED UPON THE FACTUAL FINDING COUPLED WITH THE APPROPRIATE LEGAL STANDARD THAT MR. HESS IS NOT A COINVENTOR.

64

ON COUNT 2, THAT JUDGMENT WILL BE IN FAVOR OF DEFENDANT AND AGAINST MR. HESS BECAUSE SINCE I'M FINDING HE IS NOT A COINVENTOR, HE CERTAINLY DOES NOT HAVE A CAUSE OF ACTION FOR INTERFERENCE WITH THE ... WITH HIS BUSINESS OPPORTUNITIES AS AN ALLEGED COINVENTOR.

I AM ALSO FINDING FOR THE DEFENDANT AND AGAINST THE PLAINTIFF ON THE COUNTERCLAIMS, CERTAINLY INSOFAR AS THEY SEEK A DETERMINATION OF WHO IS THE COINVENTOR.

IN 93-3438, I HAVE FORGOTTEN FOR THE MOMENT WHAT ALL OF THE CLAIMS ARE IN THAT ACTION, BUT CERTAINLY INSOFAR AS THEY ARE AN ACTION BY ACS AGAINST MR. HESS, AND PERHAPS A COUNTERCLAIM BACK BY HIM, I THINK IT'S JUST A RECIPROCAL OF THE DECISIONS THAT I HAVE MADE IN 92-1956.

SO I WILL ASK THE DEFENDANTS TO PROVIDE PROPOSED FORMS OF JUDGMENT FOR THOSE TWO CASES. THE FORMS OF JUDGMENT SHOULD

NEEDN'T RECITE ALL THE REASONS THAT I HAVE GONE THROUGH HERE, YOU CAN SIMPLY STATE IN THERE THAT I DID STATE MY REASONS ON THE RECORD IN OPEN COURT AND THEY ARE CONTAINED IN THE REPORTER'S TRANSCRIPT, AND I DON'T THINK YOU NEED TO MAKE ANY FURTHER REPUTATION — NOT MAKE ANY FURTHER RECITATION OF THE REASONING.

OF COURSE, PLEASE SUBMIT YOUR PROPOSED FORM OF JUDGMENT TO MR. ROCKEY BEFORE YOU SUBMIT THEM TO ME.

ALL RIGHT. WELL, THANK YOU FOR YOUR EXCELLENT PRESENTATION ON BOTH SIDES OF THE CASE. I KNOW IT'S

65

DISAPPOINTING TO MR. HESS AND DISAPPOINTING TO PLAINTIFFS, BUT YOU ALL KNOW THAT IS WHAT COURTS ARE HERE FOR, AND THAT IS MY NECESSITY TO MAKE A DECISION. I THINK IT WAS PRESENTED IN GOOD FAITH AND WITH GREAT COMPETENCE. I THINK YOU BOTH HAVE DONE AN EXCELLENT JOB.

I PROBABLY HAVE NOT HEARD THE END OF IT, BUT WE'LL AT LEAST GET IT OUT OF THIS COURT AND INTO ANOTHER.

THANK YOU, COUNSEL.

MR. ROCKEY: THANK YOU, YOUR HONOR.

(PROCEEDINGS ADJOURNED.)

SIMPSON — DIRECT/ROCKEY

Q. WHAT WAS THE PROBLEM?

A. WELL ... WE WOULD HAVE TO HEAT THE TEFLON TO VERY HIGH TEMPERATURES TO — SO THAT WHEN WE PRESSURIZED IT, WE WOULD TRY TO BLOW THE BALLOONS, AND WE WERE BLOWING THEM IN MOLDS, AND ... JUST WASN'T WORKING.

Q. OKAY. DID YOU EVER SUCCEED IN MAKING A BALLOON AT ALL FROM EITHER PVC OR TEFLON?

A. OH, YEAH. UH-HUH.

Q. YOU COULD MAKE ONE; YOU JUST WEREN'T SATISFIED WITH IT, I TAKE IT.

A. THAT'S RIGHT.

Q. AT THIS. ... THIS POINT WERE YOU BEGINNING TO EXPERIENCE FRUSTRATION?

A. NO, NOT AT ALL.

Q. YOU WERE NOT?

A. NO. HUH-UH.

Q. YOU HAD TRIED TWO DIFFERENT PLASTIC MATERIALS AND YOU WERE NOT SUCCESSFUL WITH EITHER ONE OF THEM.

A. THAT'S RIGHT.

Q. DID YOU CONTINUE YOUR SEARCH FOR PLASTIC MATERIALS?

A. ABSOLUTELY.

Q. AND WHAT HAPPENED WAS THAT YOU WERE — YOU KNEW A ... A GENTLEMAN ON THE STAFF AT STANFORD BY THE NAME OF BILL SANDERS, DIDN'T YOU?

A. THAT IS CORRECT.

FIT ONTO THE INNER TUBE, TO AVOID THE NECESSITY OF USING ANY ADHESIVE; CORRECT?

A. THAT'S CORRECT.

Q. IN FACT, THE PATENT DESCRIBES A TECHNIQUE BY WHICH YOU CAN HEAT THIS DISTAL END OF THE CATHETER TO EFFECT THAT SHRINK FITTING, WITHOUT TRANSMITTING ANY OF THAT HEAT TO THE BALLOON ITSELF.

CORRECT?

A. I DON'T RECALL THAT SPECIFICALLY. BUT I'M CERTAIN — YES.

Q. OKAY. AND THE IDEA FOR SHRINK FITTING THE OUTER TUBE ONTO THE INNER TUBE TO EFFECT THAT SEAL WAS A CONTRIBUTION THAT MR. HESS MADE, WASN'T IT?

A. IT IS A — A CONTRIBUTION THAT HE HELPED US WITH. THERE'S NO DOUBT ABOUT THAT, YEAH.

Q. AS A MATTER OF FACT, YOU HAD ... PROPOSED USING ADHESIVES IN THIS AREA, HAD YOU NOT?

A. I'M NOT SAYING THAT WE PROPOSED IT. WE TRIED IT. AND IT ... WAS UNSATISFACTORY.

SO WE CONTACTED MR. HESS, AND ASKED HIM FOR SOME ADVICE ON HOW TO

IMPROVE THE ADHESIVES. AND HE SAID HE WOULD JUST LEAVE THE ADHESIVES OUT.

Q. SO WOULD YOU AGREE THAT MR. HESS MADE A CONTRIBUTION TO THE CATHETER IN RESPECT TO THE USE OF SHRINK FITTING WITHOUT THE USE OF AN ADHESIVE IN THE DISTAL END?

A. YEAH, I WOULD AGREE THAT HE GAVE US SOME ADVICE ON — ON

SIMPSON — DIRECT/ROCKEY

WHAT WE COULD DO ABOUT THE ADHESIVE-RELATED PROBLEM THAT WE HAVING WERE AT THE DISTAL TIP OF THE CATHETER.

Q. WELL, DO YOU AGREE THAT THAT'S A CONTRIBUTION?

A. I DON'T KNOW HOW — I DON'T KNOW WHAT "A CONTRIBUTION" MEANS.

Q. OKAY.

NOW ... YOU HAVE NOTICED, HAVEN'T YOU, THAT SOME OF THE CLAIMS OF YOUR PATENT TALK ABOUT AN ADHESIVE-FREE SEAL AT THE DISTAL END.

A. I COULD ACTUALLY REVIEW THE PATENT, BUT I HAVE NOT REVIEWED THE PATENT IN A LONG TIME.

SO IF YOU WANT TO POINT THAT OUT TO ME —

Q. SURE.

A. — THEN I'LL BE HAPPY TO REVIEW THAT.

Q. I'D BE HAPPY TO.

LET'S TAKE — LET'S JUST TAKE A QUICK EXAMPLE OF CLAIM ... 13.

THAT'S ON THE LAST PAGE, DR. SIMPSON.

A. CLAIM 13?

Q. RIGHT.

A. UH-HUH.

(WITNESS LOOKING THROUGH DOCUMENTS.)

Q. LAST PAGE.

A. OKAY. UH-HUH.

(WITNESS READING TO HIMSELF.)

HERE THAT THE INNER MEMBER COLLAPSED AWAY FROM THE BALLOON.

SO WE HAD ANOTHER LEAKING PROBLEM AS SOON AS WE LEFT THE ADHESIVE OUT.

SO THERE'S MORE TO IT THAN JUST LEAVING THE ADHESIVE OUT TO MAKE THE THING WORK.

THE DIAMETER OF THE INNER MEMBER HAS TO BE ADJUSTED; IT HAS TO BE THICKER. SO WE HAD TO MAKE MORE CHANGES THAN JUST THAT TO KEEP THE THING FROM LEAKING.

Q. WELL, LET'S — LET'S SEE IF WE CAN TAKE THAT A STEP AT a TIME.

YOU WERE TRYING TO PUT AN ADHESIVE IN THAT AREA, WEREN'T YOU?

A. WE HAD PUT AN ADHESIVE IN THAT AREA.

Q. RIGHT.

MR. HESS SAID: NO, DON'T DO THAT.

A. THAT'S RIGHT. HE DID. ABSOLUTELY. NONDISPUTED.

Q. YOU ADOPTED HIS SUGGESTION AND YOU PUT THAT SUGGESTION IN CLAIM 13 OF YOUR PATENT, DIDN'T YOU?

A. IT SHOWS UP HERE, YES. UH-HUH.

Q. NOW, IN YOUR LETTER TO MR. COOK, WHICH IS EXHIBIT 31, WE — WE TALKED BRIEFLY ABOUT THIS ANNULAR PASSAGE (INDICATING AT EASEL) ... AND I THINK YOU KNOW THAT MR. HESS CONTENDS THAT HE MADE A SUGGESTION IN THAT DEPARTMENT; AND YOU DISPUTE IT. CORRECT?

A. THAT'S CORRECT.

SIMPSON — DIRECT/ROCKEY

BY MR. ROCKEY:

Q. AND ONE OF THE POINTS THAT YOU MADE, DR. SIMPSON, AS TO HOW THERE WAS A DIFFERENCE, WAS THAT THE '873 PATENT USED A BALLOON MADE OF A STRETCHABLE MATERIAL, SUCH AS NATURAL OR SYNTHETIC RUBBER; CORRECT?

A. THAT'S CORRECT.

Q. AND YOUR POINT WAS THAT: I LOOK AT OUR INVENTION; WE'RE USING AN IRRADIATED MODIFIED POLYOLEFIN, AND THAT DOESN'T EXPAND IN AN UNCONTROLLED MANNER; WHEREAS THIS '873 PATENT IS USING A NATURAL OR SYNTHETIC RUBBER BALLOON, AND THAT CAN EXPAND IN AN UNCONTROLLED MANNER.

WOULDN'T YOU AGREE?

A. I CERTAINLY WOULD AGREE.

Q. OKAY. AND SO THAT WAS — THAT WAS A DIFFERENCE THAT YOU WERE POINTING OUT BETWEEN THE MATERIAL OF CONSTRUCTION THAT YOU USED; NAMELY, THE IRRADIATED MODIFIED POLYOLEFIN, VERSUS THE MATERIAL OF CONSTRUCTION THAT THE '873 PATENT USED; NAMELY, NATURAL OR SYNTHETIC RUBBER.

A. THAT'S CORRECT.

Q. OKAY. IN FACT, DO YOU RECALL WRITING A PAPER ... DO YOU RECALL WRITING A PAPER ON YOUR ... CATHETER ASSEMBLY IN NINETEEN ... EIGHTY-ONE?

A. YES.

Q. I'M GOING TO HAND YOU WHAT'S BEEN MARKED AS EXHIBIT 25.

(DOCUMENTS HANDED TO THE WITNESS.)

A. (PAUSE)

YES, UH-HUH.

Q. NOW, THAT DESCRIBES A TECHNIQUE IN GENERAL TERMS OF HOW THE BALLOON CAN BE MADE, CORRECT?

A. THAT'S CORRECT.

Q. AND IT ALSO DESCRIBES IN GENERAL TERMS INFORMATION THAT MR. HESS SUPPLIED TO YOU, DOES IT NOT?

A. THAT'S CORRECT, UH-HUH.

Q. NOW, IN THE CATHETER THAT IS DESCRIBED IN YOUR PATENT, FIGURE 4, WHEN THIS IS THE OUTER TUBE IS SHRUNK FIT ONTO THE SMALLER TUBE, IS THAT ... A BONDED RELATIONSHIP IN YOUR MIND?

A. IT'S WATER TIGHT.

Q. WELL, THAT IS NOT QUITE WHAT I ASKED YOU.

A. I SEE.

I MISUNDERSTOOD THE QUESTION.

Q. IS IT BONDED? IS THE OUTER TUBE BONDED TO THE INNER TUBE TO YOUR WAY OF THINKING?

A. NO.

Q. NOW, THE MATERIALS THAT YOU USED BEFORE MR. HESS ENTERED THE PICTURE, NAMELY, PVC AND TEFLON, DO YOU HAVE ANY INFORMATION, DR. SIMPSON, AS TO WHETHER OR NOT THOSE ARE CRYSTALLINE MATERIALS?

A. MY SUSPICION IS THEY ARE NOT, BUT I DON'T KNOW.

Q. OKAY.

I WOULD LIKE TO HAND YOU ALSO WHAT'S BEEN MARKED AS

FOR POLYMER THAT WOULD WORK FOR US.

Q. THAT'S RIGHT.

A. AND SO WE FOUND THROUGH MR. HESS THAT THE RAYCHEM POLYMER REALLY WOULD WORK FOR US QUITE NICELY.

AND THIS IS SORT OF THE WAY IT WAS CHARACTERIZED.

Q. OKAY. AND SO REALLY WHERE YOU WERE AT THE TIME YOU MET MR. HESS WAS YOU KNEW WHERE YOU WANTED TO GO, BUT YOU DIDN'T HAVE ANY WAY UNTIL HESS CAME ALONG TO GET THERE.

A. WE DIDN'T HAVE THE RIGHT MATERIAL TO GET THERE. THAT'S CORRECT.

Q. OKAY.

NOW, YOU TALKED TO MR. HESS ABOUT QUITE A RANGE OF SUBJECTS, DIDN'T YOU, FROM NOT ONLY THE CRYSTALLINE MODIFIED POLYOLEFINS, BUT WHETHER YOU OUGHT TO CONSIDER A BIG COMPANY OR A SMALL COMPANY TO SELL YOUR CATHETER?

A. THAT'S CORRECT.

Q. YOU TALKED TO HIM ABOUT REGULATORY ISSUES.

A. THAT'S CORRECT.

Q. IN FACT, CAN YOU THINK OF ANY SUBJECT AREA THAT WAS RELATED TO YOUR CATHETER THAT YOU DID NOT DISCUSS WITH MR. HESS, APART FROM APPLYING FOR A PATENT?

A. I'M NOT SURE THAT WE DIDN'T DISCUSS APPLYING FOR A PATENT WITH MR. HESS.

ALL I — I DO NOT SPECIFICALLY RECALL THAT WE HAD THOSE DISCUSSIONS, BUT IT BOGGLES MY MIND THAT WITH ALL OF THE

DIDN'T HAVE THE INFORMATION YOU NEEDED TO GET TO THE POINT THAT YOU WANTED TO BE AT?

A. I THINK THAT OUR MEETINGS WITH ROB HESS, OR AT THAT TIME WE WERE TRYING TO EXPLORE DIFFERENT TYPES OF TUBING.

WE HAD BEEN — IT HAD BEEN BROUGHT TO OUR ATTENTION THAT HEAT-SHRINKABLE TUBING MAY BE SOMETHING THAT WE COULD USE. WE WANTED TO EXPLORE THAT AVENUE.

Q. OKAY.

BUT MY QUESTION TO YOU WAS A LITTLE DIFFERENT, DR. ROBERT.

WOULDN'T IT BE ACCURATE TO SAY THAT AT THE TIME JUST PRIOR TO THE TIME THAT YOU HOOKED UP WITH MR. HESS, THAT YOU KNEW WHAT YOU WANTED, BUT YOU DIDN'T KNOW HOW TO GET THERE IN TERMS OF THE MATERIALS?

A. WE WERE — WE WERE UNCERTAIN AS TO WHAT THE OPTIMAL MATERIAL WOULD BE AT THAT TIME, THAT'S CORRECT.

Q. IN FACT, THE ONLY TWO MATERIALS THAT YOU HAD WORKED WITH TO SPEAK OF WERE TEFLON AND PVC, AND NEITHER ONE OF THOSE MET YOUR NEEDS; ISN'T THAT CORRECT?

A. NEITHER ONE WAS OPTIMAL.

Q. IN FACT, THEY DIDN'T MEET YOUR NEEDS AT ALL, DID THEY?

A. TO THE EXTENT THAT WE CARRIED THEM, NO THEY DID NOT.

Q. SO YOUR PURPOSE IN GOING TO MR. HESS WAS TO SEEK SOME ASSISTANCE IN FINDING THE MATERIAL THAT WOULD WORK, HAVING FAILED TO FIND A WORKABLE MATERIAL WITH EITHER TEFLON OR PVC;

EXCERPT FROM PLAINTIFF'S TRIAL EXHIBIT NO. 25

A NEW CATHETER SYSTEM FOR CORONARY ANGIOPLASTY

John B. Simpson, PhD, MD, FACC
Donald S. Baim, MD
Edward W. Robert, MD, FACC
Donald C. Harrison, MD, FACC

Stanford, California

A new catheter system has been designed for percutaneous transluminal coronary angioplasty. An independently movable, flexible-tipped guide wire within the balloon dilation catheter facilitates selection of the involved vessel. This guide wire can be passed slowly and carefully beyond the coronary stenosis, permitting safe advancement of the balloon catheter. After testing in animal and cadaver hearts, this system was used in 53 patients (56 stenoses) with single vessel coronary artery disease, with an overall primary success rate of 64 percent. In the last 41 of these 56 cases, use of a balloon catheter with a smaller deflated diameter increased the success rate to 73 percent. In patients with lesions of the left anterior descending coronary artery, the success rate was 89 percent. Three (6 percent) of the 53 patients had complications during coronary arterial dilation that necessitated emergency coronary arterial bypass graft surgery. There were no procedure-related or late cardiac deaths. During the mean follow-up period of 8 months (range 1 to 21), there were one late death (of noncardiac causes) and no late myocardial infarctions. Clinical status was persistently improved in 31 of the 36 patients who had successful dilation. The remaining five patients experienced restenosis at the angioplasty site and return of angina pectoris within 3 months of dilation. Two of these patients had repeat coronary angioplasty with restoration of asymptomatic status, and three had elective coronary bypass graft surgery.

Transvascular intervention for the treatment of occlusive atherosclerotic peripheral vascular disease was originally introduced by Dotter and Judkins[1] and modified for use in the coronary arteries by Grüntzig et al.[2,3]. It is achieving increasing acceptance as a treatment for coronary artery disease in selected patients, with more than 1,000 cases reported in the National Institutes of Health Registry.[4]

Until recently, only the Grüntzig design of coronary arterial angioplasty catheters was available. In this design the guide wire is fixed to the tip of the balloon dilation catheter, precluding changes in the length or curvature of the guide wire after the catheter has been introduced into the coronary artery. Using a coaxial design and unique materials, we developed a fundamentally different dilation catheter system that permits independent movement and repetitive reshaping of this guide wire. This report described the basic components and techniques used to perform percutaneous transluminal coronary angioplasty with this new system and the clinical experience with our initial 53 patients.

MATERIALS

Five main components (Fig. 1) are included in the Simpson-Robert™ Vascular Dilation System (Advanced Cardiovascular Systems, Inc., Santa Clara, California). All components, including the balloon dilation catheter, are sterilized with routine gas sterilization procedures.

1. *The balloon dilation catheter (Fig. 2)* is manufactured from two concentric pieces of polyolefin tubing. The outer member is contiguous with the balloon wall and provides a deflated balloon diameter of 0.041 inch (1.04 mm). The inner member accepts a 0.018 inch (0.46 mm), Teflon®-coated, flexible-tipped guide wire. Clearance between the inner and outer members provides a channel for injection of contrast medium during balloon inflation and deflation. While the catheter is being filled

with contrast medium, a stainless steel hypodermic tubing is located within this channel to allow egress of displaced air from the balloon tip. When filling is completed, the hypodermic tubing is removed from the catheter.

From the Stanford University Medical Center, Cardiology Division, Stanford, California. Manuscript received May 4, 1981; revised manuscript received October 26, 1981, accepted October 29, 1981.

Address for reprints: John B. Simpson, PhD, MD, 750 Welch Road, Suite 120, Palo Alto, California 94304.

TYPESET VERSION OF PLAINTIFF'S TRIAL EXHIBIT NO. 31

STANFORD UNIVERSITY MEDICAL CENTER
Stanford, California 91305 * (415) 497-6141

Stanford University Hospital
Cardiology Division

April 11, 1978

Mr. Paul M. Cook, President
Raychem Corporation
300 Constitution Drive
Menlo Park, California 94025

Dear Mr. Cook:

As Postdoctoral Fellows in Cardiology at Stanford Medical Center, we have recently been challenged to design and construct a small balloon-tipped catheter for use in treating coronary artery disease. After weeks of frustration because of unsuccessful attempts to obtain assistance or advice from any of the Bay Area plastics firms, we were introduced to Mr. Rob Hess. His advice, frequently requested at unusual hours and often interrupting his weekend at home, has been tireless and critically important to our progress.

Rob introduced us to Raychem modified irradiated polyolefins, suggested numerous approaches to construction, searched diligently for special extrusions that would meet our dimensional requirements, and provided us with more than sufficient samples to construct our prototypes. All of this was done with a genuinely concerned and helpful attitude which has made our brief association with Raychem exciting and productive, and most importantly, it has led to what we consider a device which may well revolutionize the treatment of coronary artery disease in the United States.

The technique is one whereby arteriosclerotic narrowings in coronary arteries (the condition responsible for heart attacks and most instances of sudden death) are dilated by a small balloon-tipped catheter. This catheter is inserted into the anesthetized major artery of the leg and advanced by a guiding system into the coronary arteries. Once the balloon is positioned in the narrowed area, it is hydrolically expanded to compress the atherosclerotic material against the vessel wall and thus open the coronary artery. The technique is experimental but shows great promise and may present an alternative to open heart surgery in selected patients.

The only other catheters presently available for this purpose are manufactured on a small scale in Zurich, Switzerland and because of technically cumbersome assembly they are difficult to obtain in any quantity. Furthermore these catheters have several limitations rendering them far from ideal for their purpose. With Rob's help and using only Raychem materials we have constructed a catheter which has sophisticated performance characteristics while simple to manufacture.

We have enclosed photographs of the prototype catheter and an x-ray demonstrating the catheter inflated in a coronary artery of a cadaver heart. The catheter has a coaxial design; both inner and outer members are made of RNF 100 Type II. Although the initial tubing dimensions varied slightly from our specifications, we have been able to alter them accordingly with judicious heating and stretching over a mandril. Preliminary evaluation of the catheter by physicians and scientists familiar with the dilating technique confirms our feeling that our catheter is far superior to anything currently available and likely to be the catheter of choice in the future.

Although the future of the dilating procedure in general and of our catheter in particular remains modestly speculative, we feel that our endeavors to date reflect a successful meld of your

progressive, open-minded, scientifically oriented corporation with our awareness of the desired end results.

We did not want Rob's unselfish assistance to go unnoticed. Furthermore, as manufacture of the catheter system on a larger scale becomes more likely, we look forward to an even closer relationship with your firm in the future.

Our thanks again to Rob Hess and Raychem for assistance and support.

Sincerely,

/s/ John Simpson

John Simpson, M.D.

/s/ Edward Robert

Ned Robert, M.D.
Senior Postdoctoral Fellows
Cardiology Division
Stanford Medical Center

JS:mc
Enclosures
CC: Mr. R. M. Halperin

TYPESET VERSION OF PLAINTIFF'S TRIAL EXHIBIT NO. 52

REEXAMINATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE REEXAMINATION OF U.S. PATENT 4,323,071 ISSUED: APRIL 6, 1982 PATENTEE: JOHN B. SIMPSON AND EDWARD W. ROBERT FOR: VASCULAR GUIDING CATHETER ASSEMBLY AND VASCULAR DILATING CATHETER ASSEMBLY AND A COMBINATION THEREOF AND METHODS OF MAKING THE SAME	Reexamination No. 90/001,327 Examiner: Trulock Art Unit 336 Los Angeles, CA 90010

DECLARATION OF JOHN B. SIMPSON, M.D.

Hon. Commissioner of Patent and Trademarks
Washington, D.C. 20231

I, John B. Simpson, M.D. declare:

1. I am a physician in the field of interventional cardiology, and am in private practice in Palo Alto, California with Cardiovascular Medicine, a medical partnership. I was one of the founders of Advanced Cardiovascular Systems, Inc. ("ACS"). Currently, I am a consultant to ACS.

2. My educational background includes a B.S. Degree from Ohio State University, M.S. and Ph.D. Degrees from the University of Texas, and an M.D. from Duke University. My medical internship and residency were done at Duke University Hospital, and I was a fellow in cardiology for two years (1976-1978) at Stanford University School of Medicine.

3. Commencing in the fall of 1978 and continuing to the present date, I have performed a large number of percutaneous transluminal coronary angioplasty (PTCA) procedures on human patients. In this same time period, I have co-authored a number of publications and made numerous presentations to medical groups on PTCA throughout the United States and in Europe and Japan. Additionally, since 1980 I have regularly demonstrated PTCA procedures to other physicians from throughout the world, and have held teaching positions at Duke University School of Medicine and Stanford University School of Medicine where I lectured on PTCA. In 1987, I was awarded the Andreas Gruntzig award from the European Cardiology Society based on my work on PTCA.

4. I am co-inventor with Dr. Edward W. Robert on U.S. Patent No. 4,323,071 ("Simpson-Robert patent"). Confronted with a need for access to a dilatation catheter for the purpose of doing experimental studies, Dr. Robert and I set out in early 1978 to develop a suitable catheter. Our intent was to provide a catheter that had the characteristics of a low balloon profile, flexibility in the balloon region, the ability to rapidly inflate and deflate, and a balloon that would inflate to a reliably predictable size and shape and withstand the relatively high pressure needed for a PTCA procedure. It was by no means crucial to our work to have a one-piece balloon tube construction, although we worked primarily with single piece devices because they were easier to make.

5. The success we achieved in our early development work lead us to contact an attorney, in early 1978, for the purpose of preparing and filing a patent application. Such an application was filed on our behalf on May 19, 1980 and ultimately issued on April 6, 1982 as U.S. Patent No. 4,323,071.

6. I am aware of U.S. Patent No. 4,024,873 to Antoshkiw considered during the pendency of the subject reexamination. The

catheter disclosed in the Antoshkiw patent is far removed and not relevant to our invention. I have no recollection of ever believing otherwise and am firmly convinced in light of what is shown and described in Antoshkiw that I would not have ever believed otherwise at any time.

7. The Antoshkiw patent relates to a diagnostic catheter and, more particularly, to a so-called thermo-dilution catheter for determining cardiac output. The catheter assembly disclosed has concentric tubes with a balloon attached at its proximal end to the outer tube and at its distal end to the inner tube. As may be seen in the drawings (compare Figs. 1 and 2 of the Antoshkiw), the balloon is made of a stretchable material such as "natural or synthetic rubber." Provision is made for moving the inner and outer tubes relative to each other to change the shape of the balloon. An inner catheter assembly with a balloon tip is used for flow directing the catheter through the arterial system.

8. There is no doubt that the Antoshkiw type of catheter is totally unsuitable for use in angioplasty procedures. Attempted use would likely cause serious damage to the artery wall without achieving any desired effects. Sufficient force to dilate a plaque cannot be generated in a balloon made of stretchable material. Such a balloon would simply expand and deform around plaque potentially causing damage to the arterial wall. Moreover, with such a balloon or with relatively moveable inner and outer tubes, predictable balloon size and shape are not achieved.

I declare under penalty of perjury that the foregoing is true and correct. Executed at San Francisco, California on February 1, 1989.

/s/ John B. Simpson

JOHN B. SIMPSON, M.D.